REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

This Amendment and Reply is being filed within two months following the expiration of the shortened statutory period. A request for an extension of time of two months to reply and authorization for payment of the required fee accompany this filing. This Amendment and Reply is therefore timely filed.

There is confusion as to the pending claims. The Office action summary indicates that claims 1-3, 9-11 and 13-30 are pending in the application. The Detailed Action, in paragraph 1, makes reference to claims 41, 46 and 66-73. Applicant's representative notes that claim 3 was canceled in the Amendment After Final Rejection filed August 15, 2005 and that the subsequent Advisory Action indicated the amendments made after final rejection would be entered for purposes of appeal. Applicant therefore believes that claims 1, 2, 9-11 and 13-30 were pending prior to entry of the amendments presented above. In the amendments presented above, claims 9, 10 and 29 have been canceled and claims 31-33 have been added. Claims 1, 2, 11, 13-28 and 30-33 are therefore presently pending, with claims 1, 24, 27 and 30 being in independent format.

Claims 24-28 are allowed. Claim 30 was objected to as being dependent upon a rejected base claim, but the Examiner indicated claim 30 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. Claim 30 has been amended to incorporate the subject matter of claims 9 and claim 1 and should therefore be in allowable form. Dependent claims 31-33 have been added and state subject matter recited in claims 14, 15 and 20, respectively. Claim 1 has been amended to incorporate the subject matter previously recited in claim 13. Claim 13 has been amended to depend from newly independent claim 30. It is urged that no new matter has been added and that there is a clear basis in the application as filed for the amended and newly added claims.

The claim amendments have been presented for purposes of expediency in obtaining an indication of allowance of all claims and are made without prejudice to applicant's ability to make the same or similar claims in a related application. Applicant specifically does *not*

acquiesce in the outstanding prior art rejections and specifically reserves the right to prosecute claims similar to those presented previously in a related application.

Claim Rejections under 35 USC §102(b) and §103(a) – maintained

The rejection of claims 1, 3, 9. 10, 14 and 29 as being anticipated over Antoniades et al. was maintained. The rejection of claims 1, 2, 11 and 20 as being unpatentable over Antoniades et al. in view of Clark was maintained. The rejection of claims 1 and 19 as being unpatentable over Antoniades et al. in view of Whitson-Fischman et al. was maintained. It is urged that these outstanding rejections are moot in view of the amendment of claim 1 to incorporate subject matter recited in dependent claim 13.

Claims 1, 13, 15-18 and 21-23 were rejected as being unpatentable over *Antoniades et al.* in view of *Vithoulkas et al.* This rejection is respectfully traversed as it applies to applicant's pending claims.

Antoniades et al. is directed to healing an external wound in a mammal, *e.g.*, a human patient, by applying to the wound an effective amount of a composition that includes a combination of purified PDGF and purified IL-1, or purified IGF-1 and purified IL-1. *See*, Col. 2, lines 10-14. The compositions of *Antoniades et al.* are prepared using a pharmaceutically acceptable carrier substance, e.g. commercially available inert gels, or membranes, or liquids. *See*, Col. 2, lines 26-29. The disclosure and teachings of *Antoniades et al.* are directed, exclusively, to the treatment of external wounds, *e.g.* bed sores and burns, with the combination compositions.

Applicant's independent claim 1, as amended, recited specific homeopathic potencies of IGF-1 selected from the group consisting of: 6X, 6C, 15X, 12C, 30C, 100C, 200C and 1M (1000C). Homeopathic potencies, as evidenced by applicant's specification and the materials of record in the prosecution of this application relating to homeopathy and homeopathic preparations, are made using specialized and standardized techniques involving both serial dilutions and serial succussions. It is the preparatory process, and not merely the highly dilute concentration, that renders a preparation a ***homeopathic potency***. Preparation of homeopathic potencies is described, for example, in VITHOULKAS, George; "The Science of Homeopathy," pp. 157-167 (1980 Grove Press, New York); LEROY, Debra; "Potencies,"

www.medicinegarden.com/Homeopathy/Potencies (1998), printed 10/16/2000; BELLAVITE, Paolo M.D., et al.; "Homeopathy – A Frontier in Medical Science," pp. 11-12 (1995 North Atlantic Books, California). These references were listed in the Evidence Appendix accompanying the applicant's Appeal Brief, and copies of the references were provided.

There is no teaching or suggestion whatsoever in *Antoniades et al.* that the compositions are prepared homeopathically to produce homeopathic potencies. There is no description, either expressly or inherently, of homeopathic potencies, or of serial dilutions and serial succussions. No homeopathic nomenclature is used. There is no mention of the possibility or desirability of homeopathic preparations. *Vithoulkas et al.* describe standard protocols and nomenclatures for homeopathic potencies without reference to or suggestion of specific homeopathic compositions. *Vithoulkas et al.* do not disclose homeopathic potencies of IGF-1 or of other growth factors or related compositions.

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art. *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (Fed. Cir. 2005); *see* 35 U.S.C. § 103. In determining whether a combination of elements is non-obvious, it must be assessed whether, in fact, an artisan of ordinary skill in the art at the time of invention, with no knowledge of the claimed invention, would have some motivation to combine the teachings of one reference with the teachings of another reference. *Id.*

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP 2142 citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As articulated by the Examiner, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. Antoniades et al. indicate that the use of IGF-1, in combination with another composition, formulated for topical application, facilitates the wound healing process. *Vithoulkas et al.* describe the derivation and standardized preparation of homeopathic potencies for use in therapeutic methods. The disclosure of *Vithoulkas et al.* is directed to achieving reproducible results, without reference to any specific materials or compositions. The Examiner reasons that the motivation to use IGF-1 in homeopathic potencies is provided by Antoniades showing that IGF-1, in combination with another composition, facilitates wound healing. This reasoning is flawed. The fact that a substance is used in a topical formulation to facilitate wound healing does ***not*** motivate one of ordinary skill in the art to make homeopathic preparations of specified potencies of IGF-1 suitable for oral administration. The Examiner also reasons that there is a reasonable expectation of success for the combination because *Vithoulkas et al.* describe the standardized homeopathic formulations with reference to use in "therapeutic methods." This reasoning is also flawed. The fact that one reference discloses standardized preparatory techniques for use in therapeutic methods does not provide a reasonable expectation of success that any substance or composition that has a therapeutic indication may be prepared using the standardized technique and would have therapeutic properties. It is submitted that the Examiner has not made a *prima facie* showing of obviousness.

Applicant finds no motivation, in either of the references, or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the teachings of the individual references in the manner suggested by the Examiner. This rejection cannot be sustained.

Concluding Remarks

It is submitted that pending claims 1, 2, 11, 13-28 and 30-33 are all in allowable form and early allowance is respectfully solicited. Should the Examiner have any concerns regarding the subject patent application, he is respectfully invited to telephone the undersigned at 206.382.1191.

Respectfully submitted,

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